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EXAMINER	
CROW, ROBERT THOMAS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,977	ARNOLD ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/08; 4/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed 12 April 2010 in which the specification and claims 6-7 and 19-20 were amended, claims 34-36 were canceled, and no new claims were added.

2. The amendments to the claims have been thoroughly reviewed and entered.

3. The amendments to the specification filed 12 April 2010 are a duplicate copy of the amendments field 16 November 2010, which were entered previously. Therefore, the amendments to the specification filed 12 April 2010 are not entered.

Election/Restrictions

4. Applicant's election of Group I in the reply filed on 16 November 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

5. It is also noted that Applicant's election included cancellation of Group II, claims 34-39. Therefore, claims 1-33 are under prosecution.

Information Disclosure Statement

6. The Information Disclosure Statements filed 3 January 2008 and 13 April 2005 are acknowledged and have been considered.

Claim Interpretation

7. As noted in the Requirement for Restriction mailed 14 August 2009, claims 14-33 are drawn to a "system." The specification teaches a "system" wherein the "system" is defined in terms of **structural** limitations (e.g., pages 5 and 7-8 and Figure 1). In addition, claims 14-33 recite **structural** limitations of the "system." Thus, the "system" is interpreted to encompass any collection of reagents and parts used together that are not necessarily part of a completely integrated single unitary device. Any further interpretation of the word is considered an "intended use" and does not impart any further structural limitation on the claimed subject matter.

8. It is noted that the preamble be independent claim 1 reads "For use in a system including a light source, and a light detector, for measuring one or more of at least two target substances including a chain of nucleotides, a sensor comprising…." The terms "for use" and "for measuring" clearly indicated that the light source, and detector are not required of the claimed sensor. The courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch &Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in the preamble to the claim (e.g., all the text of the preamble preceding the phrase "a

sensor comprising") fail to define additional structural elements of the claimed sensor. Thus, only those structural limitations appearing after the phrase "a sensor comprising" are required by the claim. See MPEP § 2114.

Claim Objections

9. Claims 5 and 18 are objected to because of the following informalities: each of the claims recited “a InP” in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 6-7 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 19 are indefinite in the recitation "wherein at least one of the target substances is DNA” at the end of each of the claims, and claims 7 and 20 are indefinite in the recitation “wherein at least one of the target substances is RNA” at the end of each of the claims. The recitation is indefinite because the claims define the target substances, and therefore describe an intended use of the sensor and are not part of the claimed device. Thus, the claimed sensors are indefinite because the sensor of claims 6 and 19 would be infringed upon if the sensor is bound to a target DNA but is not infringed upon if it is bound to a DNA intercalator. Similarly, the sensor of claims 7

and 20 would be infringed upon if the sensor is bound to a target RNA but is not infringed upon if it is bound to an RNA binding protein. Thus, the metes and bounds are not sufficiently clear so as to define the bo9unds of the patent protection desired, and the claims are indefinite.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-3, 6-9, 14-16, 19-22, and 31 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Maleki et al (U.S. Patent Application Publication No. US 2002/0097401, filed 8 August 2001).

Regarding claim 1, Maleki et al teach a sensor comprising an optical carrier in the form of an optical fiber (paragraph 0032). The sensor further comprises two or more optical cavities in the form of multiple WGM (i.e., whisper gallery mode) cavities that form a detector array (paragraph 0048). The optical cavities are optically coupled to the optical carrier because signals from the WGM are optically detected (Figure 3). The exterior surface of the WGM (i.e., optical) cavity is coated with a reactive surface in the

form of a DNA molecule (i.e., an oligonucleotide; paragraph 0045). Because each WGM (i.e., optical) cavity is coated with a different reactive surface for a different analyte (i.e., a different DNA oligonucleotide for a different DNA analyte; paragraphs 0048 and 0045), each of the optical cavities has a surface having an oligonucleotide complementary to one of the at least two target substances. Application of light causes resonance within each of the optical cavities (paragraph 0006).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not posses characteristic relied on" (205 USPQ 594, second column, first full paragraph). While Maleki et al do not explicitly teach hybridization of the target substance to oligonucleotides shifts the resonance (which is detected to determine a measurement of the target substance), Maleki et al teach the analogous process of binding an antigen to an immobilized antibody causes a shift in the resonance, which is detected (paragraph 0046). Thus, the sensor of Maleki et al exhibits the same behavior when nucleic acid interactions are used instead of antibody/antigen interactions.

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing a target substance and measuring the resonance shift) fail to define additional structural elements of the claimed sensor. Because Maleki et al teach all of the required

structural limitations of the claimed sensor, the claim is anticipated by Maleki et al. See MPEP § 2114.

Regarding claim 2, Maleki et al teach the sensor of claim 1, wherein the optical carrier is an optical fiber (paragraph 0032).

Regarding claim 3, Maleki et al teach the sensor of claim 1, wherein at least one of the optical cavities is a microsphere; namely, the WGM is microsphere (Figures 1-2 and paragraph 0008).

Regarding claims 6-7, the device of claim 1 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing to a DNA [i.e., claim 6] or hybridizing to an RNA [i.e., claim 7]) refer to the target and thus fail to define additional structural elements of the claimed sensor because the targets are not part of the claimed sensor. Because Maleki et al teach all of the required structural limitations of the claimed sensor, the claim is anticipated by Maleki et al.

Regarding claims 8-9, the device of claim 1 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., causing a shift upon target binding) refer to a use of the sensor and thus fail to define additional structural elements of the claimed sensor. Because Maleki et al teach all of the required structural limitations of the claimed sensor, the claim is anticipated by Maleki et al.

In addition, it is reiterated that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject

matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Maleki et al do not explicitly teach a ten-fold shift I.e., claim 9) for single nucleotide mismatches (i.e., claim 8), it is believed that this is an inherent property of the claimed sensor.

Regarding claim 14, Maleki et al teach a system comprising a light source and a light detector in the form of an optical detection module (Figure 2). The system further comprises a sensor comprising an optical carrier in the form of a support having a chamber (paragraph 0035). The sensor further comprises two or more optical cavities in the form of multiple WGM (i.e., whisper gallery mode) cavities that form a detector array (paragraph 0048). The optical cavities are optically coupled to the optical carrier because signals from the WGM are optically detected (Figure 2). The exterior surface of the WGM (i.e., optical) cavity is coated with a reactive surface in the form of a DNA molecule (i.e., an oligonucleotide; paragraph 0045). Because each WGM (i.e., optical) cavity is coated with a different reactive surface for a different analyte (i.e., a different DNA oligonucleotide for a different DNA analyte; paragraphs 0048 and 0045), each of the optical cavities has a surface having an oligonucleotide complementary to one of the at least two target substances. Application of light causes resonance within each of the optical cavities (paragraph 0006). Maleki et al also teach the system comprise a processor for determining a measurement of the target substance using a shift in the

resonances detected; namely, a signal processing module (Figure 2 and paragraph 0031).

As noted above, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Maleki et al do not explicitly teach hybridization of the target substance to oligonucleotides shifts the resonance (which is detected to determine a measurement of the target substance), Maleki et al teach the analogous process of binding an antigen to an immobilized antibody causes a shift in the resonance, which is detected (paragraph 0046). Thus, the system of Maleki et al exhibits the same behavior when nucleic acid interactions are used instead of antibody/antigen interactions.

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing a target substance and measuring the resonance shift) fail to define additional structural elements of the claimed sensor. Because Maleki et al teach all of the required structural limitations of the claimed system, the claim is anticipated by Maleki et al.

Regarding claim 15, Maleki et al teach the system of claim 14, wherein the optical carrier is an optical fiber (paragraph 0032).

Regarding claim 16, Maleki et al teach the system of claim 14, wherein at least one of the optical cavities is a microsphere; namely, the WGM is microsphere (Figure 1 and paragraph 0008).

Regarding claims 19-20, the system of claim 14 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing to a DNA [i.e., claim 19] or hybridizing to an RNA [i.e., claim 20]) refer to the target and thus fail to define additional structural elements of the claimed system, because the targets are not part of the claimed system. Because Maleki et al teach all of the required structural limitations of the claimed system, the claim is anticipated by Maleki et al.

Regarding claims 21-22, the system of claim 14 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., causing a shift upon target binding) refer to a use of the system and thus fail to define additional structural elements of the claimed system. Because Maleki et al teach all of the required structural limitations of the claimed system, the claim is anticipated by Maleki et al.

In addition, it is reiterated that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Maleki et al do not explicitly teach a ten-fold shift (i.e.,

claim 22) for single nucleotide mismatches (i.e., claim 21), it is believed that this is an inherent property of the claimed system.

Regarding claim 31, Maleki et al teach the system of claim 31, wherein the optical carrier includes a plurality of optical carriers; namely, the system comprises two optical fibers (paragraph 0032 and Figure 3A).

14. Claims 1-2, 4-15, 17-27, 31, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyd et al (U.S. Patent Application Publication No. US 2004/0023396 A1, filed 14 November 2002).

Regarding claim 1, Boyd et al teach a sensor comprising optical carrier 14 and an optical cavity in the form of a resonator 20 (Figure 1A). The sensor has multiple resonators (i.e., optical cavities) on the carrier (i.e., waveguide; paragraph 0046). Each resonator surface has different oligonucleotide probes thereon (i.e., for different target nucleotide chain analytes; paragraphs 0030-0033). Light is applied to the carrier, and a shift (i.e., change) in resonance is detected (Abstract).

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing a target substance and measuring the resonance shift) fail to define additional structural elements of the claimed sensor. Because Boyd et al teach all of the required structural limitations of the claimed sensor, the claim is anticipated by Boyd et al.

Regarding claim 2, Boyd et al teach the sensor of claim 1, wherein the optical carrier is an optical fiber; namely, the waveguide comprises a fiber (paragraph 0025).

Regarding claims 4-5, Boyd et al teach the sensor of claim 1, wherein the optical cavity is either a toroidal (i.e., ring-shaped) microcavity (i.e., claim 4, Abstract), or a microdisk (Abstract), wherein the microdisk in an InP microdisk (i.e., claim 5; paragraph 0022).

Regarding claims 6-7, the device of claim 1 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing to a DNA [i.e., claim 6] or hybridizing to an RNA [i.e., claim 7]) refer to the target and thus fail to define additional structural elements of the claimed sensor because the targets are not part of the claimed sensor. Because Boyd et al teach all of the required structural limitations of the claimed sensor, the claim is anticipated by Boyd et al.

Regarding claims 8-9, the device of claim 1 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., causing a shift upon target binding) refer to a use of the sensor and thus fail to define additional structural elements of the claimed sensor. Because Boyd et al teach all of the required structural limitations of the claimed sensor, the claim is anticipated by Boyd et al.

In addition, it is reiterated that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses

characteristic relied on. While Boyd et al do not explicitly teach a ten-fold shift I.e., claim 9) for single nucleotide mismatches (i.e., claim 8), it is believed that this is an inherent property of the claimed sensor.

Regarding claims 10-13, Boyd et al teach the sensor of claim 1, wherein the length of the oligonucleotide is at least about 7 nucleotides up to about 100 nucleotides in length (paragraph 0033), which encompasses the claimed value of 11 nucleotides (i.e., claims 10 and 12) and 27 nucleotides (i.e., claims 11 and 13).

Regarding claim 14, Boyd et al teach a system comprising a light source and a detector (Figure 1) and a sensor comprising optical carrier 14 and an optical cavity in the form of a resonator 20 (Figure 1A). The sensor has multiple resonators (i.e., optical cavities) on the carrier (i.e., waveguide; paragraph 0046). Each resonator surface has different oligonucleotide probes thereon (i.e., for different target nucleotide chain analytes; paragraphs 0030-0033). Light is applied to the carrier, and a shift (i.e., change) in resonance is detected (Abstract). The system also comprises a processor in the form of a device that determines electrical measurements based on the optical signal form the optical detector (paragraph 0044).

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing a target substance and measuring the resonance shift) fail to define additional structural elements of the claimed sensor. Because Boyd et al teach all of the required structural limitations of the claimed sensor, the claim is anticipated by Boyd et al.

Regarding claim 15, Boyd et al teach the system of claim 14, wherein the optical carrier is an optical fiber; namely, the waveguide comprises a fiber (paragraph 0025).

Regarding claims 17-18, Boyd et al teach the system of claim 14, wherein the optical cavity is either a toroidal (i.e., ring-shaped) microcavity (i.e., claim 17, Abstract), or a microdisk (Abstract), wherein the microdisk in an InP microdisk (i.e., claim 18; paragraph 0022).

Regarding claims 19-20, the system of claim 14 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing to a DNA [i.e., claim 19] or hybridizing to an RNA [i.e., claim 20]) refer to the target and thus fail to define additional structural elements of the claimed system because the targets are not part of the claimed system. Because Boyd et al teach all of the required structural limitations of the claimed system, the claim is anticipated by Boyd et al.

Regarding claims 21-22, the system of claim 141 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., causing a shift upon target binding) refer to a use of the system, and thus fail to define additional structural elements of the claimed system. Because Boyd et al teach all of the required structural limitations of the claimed system, the claim is anticipated by Boyd et al.

In addition, it is reiterated that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is

identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Boyd et al do not explicitly teach a ten-fold shift (i.e., claim 9) for single nucleotide mismatches (i.e., claim 8), it is believed that this is an inherent property of the claimed system.

Regarding claims 23-26, Boyd et al teach the system of claim 14, wherein the length of the oligonucleotide is at least about 7 nucleotides up to about 100 nucleotides in length (paragraph 0033), which encompasses the claimed value of 11 nucleotides (i.e., claims 23 and 25) and 27 nucleotides (i.e., claims 24 and 26).

Regarding claim 27, Boyd et al teach the system of claim 14, wherein the processor (i.e., monitoring system) determines the combination of a shift in characteristic of the resonance detected and the effective refractive index of the resonator (paragraphs 0044 and 0046).

As noted above, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Boyd et al do not explicitly the change in refractive index is of a solution and the optical cavity, the processor does measure the effective refractive index of the resonator as discussed above. Thus, when the resonator is contacted with a solution of the target substance, the processor is capable of performing the claimed function.

In addition, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., measure a change in the refractive index upon addition of the solution) refer to a use of the system, and thus fail to define additional structural elements of the claimed system. Because Boyd et al teach all of the required structural limitations of the claimed system, the claim is anticipated by Boyd et al.

Regarding claim 31, Boyd et al teach the system of claim 14, wherein the system comprises a plurality of optical fibers (i.e., waveguides; paragraph 0009).

Regarding claim 33, Boyd et al teach the system of claim 14, wherein there are at least two detectors, one light source, and two fibers are coupled to the light source but are coupled to different detectors (Figure 1C).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-4, 6-9, 14-17, 19-22, and 31-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Hunziker et al (U.S. Patent No. 6,583,399 B1, issued 24 June 2003; filed 22 November 2000) and Maleki et al (U.S. Patent Application Publication No. US 2002/0097401, filed 8 August 2001)

Regarding claim 1, Hunziker et al teach a sensor comprising an optical carrier in the form of optical coupler 14, and at least two optical cavities in the form of optical resonators 16 (Figure 2G and column 7, lines 1-30). Each optical resonator is a microsphere or a ring (column 5, lines 50-60), and is optically coupled to the optical carrier and has oligonucleotides complementary to a target substance thereon (Figure 2B). The sensor is an array of couplers wherein each coupler linked to a resonator that is modified to interact with a unique substance (i.e., target substance; column 3, lines 50-60). Light is applied so that resonance is excited and shifted (i.e., altered) upon interaction with a specific substance (i.e., target), which is detected (Abstract).

As noted above, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic

relied on. While Hunziker et al do not explicitly teach hybridization of the target substance to oligonucleotides shifts the resonance (which is detected to determine a measurement of the target substance), Hunziker et al teach the analogous process of binding an target to an immobilized substance causes a shift in the resonance, which is detected (Abstract). Thus, the sensor of Hunziker et al exhibits the same behavior when nucleic acid interactions are used.

While Hunziker et al teach the modifier is an oligonucleotide (i.e., DNA molecule) that binds to a complementary (i.e., target) DNA molecule (column 6, lines 5-25), and that the sensor is an array of couplers wherein each coupler linked to a resonator that is modified to interact with a unique substance (i.e., target substance; column 3, lines 50-60), Hunziker et al do not explicitly teach two different oligonucleotides on the optical carriers for each of two target nucleic acids.

However, Maleki et al teach a sensor comprising an optical carrier in the form of an optical fiber (paragraph 0032). The sensor further comprises two or more optical cavities in the form of multiple WGM (i.e., whisper gallery mode) cavities that form a detector array (paragraph 0048). The optical cavities are optically coupled to the optical carrier because signals from the WGM are optically detected (Figure 3). The exterior surface of the WGM (i.e., optical) cavity is coated with a reactive surface in the form of a DNA molecule (i.e., an oligonucleotide; paragraph 0045). Because each WGM (i.e., optical) cavity is coated with a different reactive surface for a different analyte (i.e., a different DNA oligonucleotide for a different DNA analyte; paragraphs 0048 and 0045), each of the optical cavities has a surface having an oligonucleotide complementary to

one of the at least two target substances. Application of light causes resonance within each of the optical cavities (paragraph 0006). The plurality of analytes are measured to provide for redundancy and blanks all in one sensor (paragraph 0048). Thus, Maleki et al teach the known technique of having different oligonucleotides on different optical carriers for different target nucleic acids.

As noted above, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Maleki et al do not explicitly teach hybridization of the target substance to oligonucleotides shifts the resonance (which is detected to determine a measurement of the target substance), Maleki et al teach the analogous process of binding an antigen to an immobilized antibody causes a shift in the resonance, which is detected (paragraph 0046). Thus, the sensor of Maleki et al exhibits the same behavior when nucleic acid interactions are used instead of antibody/antigen interactions.

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing a target substance and measuring the resonance shift) fail to define additional structural elements of the claimed sensor. Because the prior art teaches all of the required structural limitations of the claimed system, the claim is obvious over the prior art.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made that the combination of the prior art of Hunziker et al with the prior art of Maleki et al would result in a sensor having different oligonucleotides on different optical carriers for different target nucleic acids to arrive at the instantly claimed sensor with a reasonable expectation of success. The ordinary artisan would have been motivated to make the combination because said combination would have resulted in a sensor having the added advantage of allowing measurement of a plurality of analytes while provide for redundancy and blanks all in one sensor as taught by Maleki et al (paragraph 0048). In addition, it would have been obvious to the ordinary artisan that the known technique of having different oligonucleotides on different optical carriers for different target nucleic acids could have been applied to the sensor of Maleki et al and Hunziker et al with predictable results because the known technique of having different oligonucleotides on different optical carriers for different target nucleic acids predictably results in a sensor useful for assaying multiple nucleic acid targets.

Regarding claim 2, the sensor of claim 1 is discussed above. Hunziker et al teach the coupler is an optical fiber in the form of a fiber waveguide (column 5, lines 35). Maleki et al also teach the optical carrier is an optical fiber (paragraph 0032).

Regarding claim 3, the sensor of claim 1 is discussed above. Hunziker et al teach the optical resonator is a microsphere (column 5, lines 50-60). Maleki et al also teach the WGM is microsphere (Figures 1-2 and paragraph 0008).

Regarding claim 4, the sensor of claim 1 is discussed above. Hunziker et al teach the optical resonator is a ring (column 5, lines 50-60).

Regarding claims 6-7, the device of claim 1 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing to a DNA [i.e., claim 6] or hybridizing to an RNA [i.e., claim 7]) refer to the target and thus fail to define additional structural elements of the claimed sensor because the targets are not part of the claimed sensor. Because the prior art teaches all of the required structural limitations of the claimed sensor, the claim is obvious over the prior art.

In addition, with respect to claim 6, Hunziker et al teach the target is a DNA (i.e., claim 6; column 6, lines 5-25).

Regarding claims 8-9, the device of claim 1 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., causing a shift upon target binding) refer to a use of the sensor and thus fail to define additional structural elements of the claimed sensor. Because the prior art teaches all of the required structural limitations of the claimed sensor, the claim is obvious over the prior art.

In addition, it is reiterated that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses

characteristic relied on. While the prior art does not explicitly teach a ten-fold shift (i.e., claim 9) for single nucleotide mismatches (i.e., claim 8), it is believed that this is an inherent property of the claimed sensor.

Regarding claim 14, Hunziker et al teach a system comprising a light source 12 and a light detector 18a (Figure 1 and column 4, lines 35-65). The system includes sensor comprising an optical carrier in the form of optical coupler 14, and at least two optical cavities in the form of optical resonators 16 (Figure 2G and column 7, lines 1-30). Each optical resonator is a microsphere or a ring (column 5, lines 50-60), and is optically coupled to the optical carrier and has oligonucleotides complementary to a target substance thereon (Figure 2B). The sensor is an array of couplers wherein each coupler linked to a resonator that is modified to interact with a unique substance (i.e., target substance; column 3, lines 50-60). Light is applied so that resonance is excited and shifted (i.e., altered) upon interaction with a specific substance (i.e., target), which is detected (Abstract). The system also comprises a processor in the form of a column 5, computer which detects the shift in resonance (i.e., changes of transmitted light; Figure 1 and column 4, lines 35-65).

As noted above, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Hunziker et al do not explicitly teach hybridization of the target

substance to oligonucleotides shifts the resonance (which is detected to determine a measurement of the target substance), Maleki et al teach the analogous process of binding an target to an immobilized substance causes a shift in the resonance, which is detected (Abstract). Thus, the system of Hunziker et al exhibits the same behavior when nucleic acid interactions are used.

While Hunziker et al teach the modifier is an oligonucleotide (i.e., DNA molecule) that binds to a complementary (i.e., target) DNA molecule (column 6, lines 5-25), and that the sensor is an array of couplers wherein each coupler linked to a resonator that is modified to interact with a unique substance (i.e., target substance; column 3, lines 50-60), Hunziker et al do not explicitly teach two different oligonucleotides on the optical carriers for each of two target nucleic acids.

However, Maleki et al teach a system comprising a light source and a light detector in the form of an optical detection module (Figure 2). The system further comprises a sensor comprising an optical carrier in the form of a support having a chamber (paragraph 0035). The sensor further comprises two or more optical cavities in the form of multiple WGM (i.e., whisper gallery mode) cavities that form a detector array (paragraph 0048). The optical cavities are optically coupled to the optical carrier because signals from the WGM are optically detected (Figure 2). The exterior surface of the WGM (i.e., optical) cavity is coated with a reactive surface in the form of a DNA molecule (i.e., an oligonucleotide; paragraph 0045). Because each WGM (i.e., optical) cavity is coated with a different reactive surface for a different analyte (i.e., a different DNA oligonucleotide for a different DNA analyte; paragraphs 0048 and 0045), each of

the optical cavities has a surface having an oligonucleotide complementary to one of the at least two target substances. Application of light causes resonance within each of the optical cavities (paragraph 0006). Maleki et al also teach the system comprise a processor for determining a measurement of the target substance using a shift in the resonances detected; namely, a signal processing module (Figure 2 and paragraph 0031).

Maleki et al also teach the plurality of analytes are measured to provide for redundancy and blanks all in one sensor (paragraph 0048). Thus, Maleki et al teach the known technique of having different oligonucleotides on different optical carriers for different target nucleic acids.

As noted above, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Maleki et al do not explicitly teach hybridization of the target substance to oligonucleotides shifts the resonance (which is detected to determine a measurement of the target substance), Maleki et al teach the analogous process of binding an antigen to an immobilized antibody causes a shift in the resonance, which is detected (paragraph 0046). Thus, the system of Maleki et al exhibits the same behavior when nucleic acid interactions are used instead of antibody/antigen interactions.

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing a target substance and measuring the resonance shift) fail to define additional structural elements of the claimed sensor. Because the prior art teaches all of the required structural limitations of the claimed system, the claim is obvious over the prior art.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made that the combination of the prior art of Hunziker et al with the prior art of Maleki et al would result in a system having different oligonucleotides on different optical carriers for different target nucleic acids to arrive at the instantly claimed system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the combination because said combination would have resulted in a system having the added advantage of allowing measurement of a plurality of analytes while provide for redundancy and blanks all in one sensor as taught by Maleki et al (paragraph 0048). In addition, it would have been obvious to the ordinary artisan that the known technique of having different oligonucleotides on different optical carriers for different target nucleic acids could have been applied to the system of Maleki et al and Hunziker et al with predictable results because the known technique of having different oligonucleotides on different optical carriers for different target nucleic acids predictably results in a system useful for assaying multiple nucleic acid targets.

Regarding claim 15, the system of claim 14 is discussed above. Hunziker et al teach the coupler is an optical fiber in the form of a fiber waveguide (column 5, lines 35). Maleki et al also teach the optical carrier is an optical fiber (paragraph 0032).

Regarding claim 16, the system of claim 14 is discussed above. Hunziker et al teach the optical resonator is a microsphere (column 5, lines 50-60). Maleki et al also teach the WGM is microsphere (Figures 1-2 and paragraph 0008).

Regarding claim 17, the system of claim 14 is discussed above. Hunziker et al teach the optical resonator is a ring (column 5, lines 50-60).

Regarding claims 19-20, the system of claim 14 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., hybridizing to a DNA [i.e., claim 6] or hybridizing to an RNA [i.e., claim 7]) refer to the target and thus fail to define additional structural elements of the claimed system because the targets are not part of the claimed system. Because the prior art teaches all of the required structural limitations of the claimed system, the claim is obvious over the prior art.

In addition, with respect to claim 19, Hunziker et al teach the target is a DNA (column 6, lines 5-25).

Regarding claims 21-22, the system of claim 14 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., causing a shift upon target binding) refer to a use of the system and thus fail to define additional structural elements of the claimed

system. Because the prior art teaches all of the required structural limitations of the claimed system, the claim is obvious over the prior art.

In addition, it is reiterated that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While the prior art does not explicitly teach a ten-fold shift (i.e., claim 22) for single nucleotide mismatches (i.e., claim 21), it is believed that this is an inherent property of the claimed system.

Regarding claim 31, the system of claim 14 is discussed above. Hunziker et al teach the system includes a plurality of optical carriers 14 (Figure 2G). Maleki et al also teach the optical carrier includes a plurality of optical carriers; namely, the system comprises two optical fibers (paragraph 0032 and Figure 3A).

Regarding claim 32, the system of claim 31 is discussed above. Hunziker et al teach each of the optical fibers 14 is coupled with at least two optical cavities 16 (Figure 2G).

18. Claims 5, 18, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunziker et al (U.S. Patent No. 6,583,399 B1, issued 24 June 2003; filed 22 November 2000) and Maleki et al (U.S. Patent Application Publication No. US 2002/0097401, filed 8 August 2001) as applied to claims 1 and 14 above, and further in view of Boyd et al (U.S. Patent No. US 2004/0023396 A1, filed 14 November 2002).

Regarding claims 5 and 18, the sensor of claim 1 and the system of claim 14 are discussed above in Section 17.

Neither Hunziker et al nor Maleki et al teach the optical cavity is a functionally equivalent InP microdisk.

However, Boyd et al teach a system having a sensor comprising optical carrier 14 and an optical cavity in the form of a resonator 20 (Figure 1A). The sensor has multiple resonators (i.e., optical cavities) on the carrier (i.e., waveguide; paragraph 0046). The optical cavity is a microdisk (Abstract), in the form of an InP microdisk (paragraph 0022). Boyd et al also teach the microdisks have the added advantage of being highly sensitive (paragraph 0010). Thus, Boyd et al teach known technique of using a functionally equivalent InP microdisk.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the sensor and system of as Hunziker et al and Maleki et al so that the optical cavity is the functionally equivalent InP microdisk taught by Boyd et al to arrive at the instantly claimed sensor and system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a sensor and system having the added advantage of using a highly sensitive functionally equivalent optical cavity as explicitly taught by Boyd et al (paragraph 0010). In addition, it would have been obvious to the ordinary artisan that the known technique of using the functionally equivalent InP microdisk of Boyd et al could have been applied to the sensor and system of as Hunziker et al and Maleki et al with predictable results

because the known technique of using the functionally equivalent InP microdisk of Boyd et al predictably results in an optical cavity useful for detection of nucleic acid reactions.

Regarding claim 27, the system of claim 14 is discussed above in Section 17.

Neither Hunziker et al nor Maleki et al teach measuring the refractive indices.

However, Boyd et al teach a system wherein the processor (i.e., monitoring system) determines the combination of a shift in characteristic of the resonance detected and the effective refractive index of the resonator (paragraphs 0044 and 0046), which allows measuring of the presence of biological materials (paragraph 0044). Thus, Boyd et al teach known technique of using processor that measures refractive indices.

As noted above, *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to prove that subject matter shown to be in the prior art does not posses characteristic relied on. While Boyd et al do not explicitly the change in refractive index is of a solution and the optical cavity, the processor does measure the effective refractive index of the resonator as discussed above. Thus, when the resonator is contacted with a solution of the target substance, the processor is capable of performing the claimed function.

In addition, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in the claim (e.g., measure a change in the refractive index upon addition of the solution) refer to a use of the system, and thus fail

to define additional structural elements of the claimed system. Because the prior art teaches all of the required structural limitations of the claimed system, the claim is obvious over the prior art.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the system of Hunziker et al and Maleki et al so that the processor determines the combination of a shift in characteristic of the resonance detected and the effective refractive index of the resonator as taught by Boyd et al to arrive at the instantly claimed system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a system having the added advantage of allowing measuring of the presence of biological materials as explicitly taught by Boyd et al (paragraph 0044). In addition, it would have been obvious to the ordinary artisan that the known technique of using processor that measures refractive indices microdisk of Boyd et al could have been applied to the system of Hunziker et al and Maleki et al with predictable results because the known technique of using processor that measures refractive indices of Boyd et al predictably results in an processor useful for detection of nucleic acid reactions.

19. Claims 10-13 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunziker et al (U.S. Patent No. 6,583,399 B1, issued 24 June 2003; filed 22 November 2000) and Maleki et al (U.S. Patent Application Publication No. US 2002/0097401, filed 8 August 2001) as applied to claims 1 and 14 above, and further in view of Thompson et al (U.S. Patent No. 6,169,194 B1, issued 2 January 2001).

Regarding claims 10-13 and 23-26, the sensor and system of claims 1 and 14 are discussed above in Section 17.

Neither Hunziker et al nor Maleki et al nor teach the length of the oligonucleotides.

However, Thompson et al teach immobilized nucleic acid probes having lengths of 10-30 bases, which have the added advantage of allowing fast analysis at low cost (column 3, lines 15-25). Thus, Thompson et al teach the known technique of using immobilized probes having lengths of 10-30 bases.

It is noted that the courts have stated where the claimed ranges "overlap or lie inside the ranged disclosed by the prior art" and even when the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have similar properties, a *prima facie* case of obviousness exists (see *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Titanium Metals Corp. of America v. Banner*, 778 F2d 775. 227 USPQ 773 (Fed. Cir. 1985) (see MPEP 2144.05.01). Therefore, the claimed ranges of 11 bases (i.e., claims 10, 12, 23, and 25) and 27 bases (i.e., claims 11, 13, 24, and 26) are an obvious variant of the 10-30 bases taught by Thompson et al.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the immobilized oligonucleotides in the sensor and system of Hunziker et al and Maleki et al so that the immobilized oligonucleotides are either 11 bases (i.e., claims 10, 12, 23, and 25) or 27 bases (i.e.,

claims 11, 13, 24, and 26) in accordance with the teachings of Thompson et al to arrive at the instantly claimed sensor and system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a sensor and system having the added advantage of allowing fast and inexpensive analysis of target analytes as explicitly taught by Thompson et al (column 3, lines 15-25). In addition, it would have been obvious to the ordinary artisan that the known technique of using immobilized probes having lengths of 10-30 (i.e., 11 or 27) bases as taught by Thompson et al could have been applied to the sensor and system of Hunziker et al and Maleki et al with predictable results because the known technique of using immobilized probes having lengths of 10-30 (i.e., 11 or 27) bases as taught by Thompson et al predictably results in probe lengths suitable for nucleic acid analysis.

20. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunziker et al (U.S. Patent No. 6,583,399 B1, issued 24 June 2003; filed 22 November 2000) and Maleki et al (U.S. Patent Application Publication No. US 2002/0097401, filed 8 August 2001) as applied to claim 14 above, and further in view of Vollmer et al (Appl. Phys. Lett., vol. 80, pages 4057-4059 (2002)).

Regarding claims 28-30, the system of claim 14 is discussed above in Section 17.

Maleki et al teach the signal obtained from the analyte is compared to that of a control signal (paragraph 0007).

Neither Hunziker et al nor Maleki et al teach measurement of polarizability (i.e., claim 29), the radius of the microsphere (i.e., claim 29), or the surface density (i.e., claim 30).

However, Vollmer et al teach a system comprising an optical (i.e., resonant) microcavity (Abstract). Vollmer et al also teach the calculation of surface density based on the excess polarizability and the radius (i.e., of a microsphere; page 4058, column 2). Vollmer et al also teach the calculation has the added advantage of verifying the surface density, which in turn established the smallest weight detectable by the system (pages 4058, column 2). Thus, Vollmer et al teach the known technique of measuring polarizability (i.e., claim 29), the radius of the microsphere (i.e., claim 29), and the surface density (i.e., claim 30).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the processor in system of Hunziker et al and Maleki et al , which measures the analyte via comparison to a control (i.e., equal volume of solution) so that the processor performs the calculation of surface density (i.e., claims 30) based on polarizability (i.e., claim 29) and the radius of the microsphere (i.e., claim 29) in accordance with the teachings of Vollmer et al to arrive at the instantly claimed system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a system having the added advantage of verifying the surface density, which in turn established the smallest weight detectable by the system, as explicitly taught by Vollmer et al (pages 4058, column 2). In addition, it

would have been obvious to the ordinary artisan that the known technique of measuring polarizability (i.e., claim 29), the radius of the microsphere (i.e., claim 29), and the surface density (i.e., claim 30) as taught by Vollmer et al could have been applied to the system of Hunziker et al and Maleki et al with predictable results because the known technique of measuring polarizability (i.e., claim 29), the radius of the microsphere (i.e., claim 29), and the surface density (i.e., claim 30) as taught by Vollmer et al predictably results in calculation of useful data for the proper operation of a biosensor.

21. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hunziker et al (U.S. Patent No. 6,583,399 B1, issued 24 June 2003; filed 22 November 2000) and Maleki et al (U.S. Patent Application Publication No. US 2002/0097401, filed 8 August 2001) as applied to claim 31 above, and further in view of Stabile et al (U.S. Patent No. 5.872,623, issues 16 February 1999).

Regarding claim 33, the system of claim 31 is discussed above in Section 17.

While Hunziker et al teach the system comprises as single light source, multiple fibers, and multiple light detectors 18A-C (Figures 1 and 2G), neither Hunziker et al nor Maleki et al teach each fiber (i.e., array locations) is coupled to a different detector.

However, Stabile et al teach a system wherein each array location has its own dedicated detector, which has the added advantage of eliminating cross-talk between the different detection sites (i.e., of the array; column 8, “Second Additional Aspect”). Thus, Stabile et al teach the known technique of having each array location coupled to a different detector.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the immobilized oligonucleotides in the system comprising a single light source and detectors of Hunziker et al and Maleki et al so that each of the optical carriers is coupled to a different detector in accordance with the teachings of Stabile et al to arrive at the instantly claimed sensor and system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a sensor and system having the added advantage of eliminating cross-talk between the different optical cavities (i.e., detection sites) of the array as taught by Stabile et al (column 8, Second Additional Aspect). In addition, it would have been obvious to the ordinary artisan that the known technique of having each array location coupled to a different detector as taught by Stabile et al could have been applied to the system of Hunziker et al and Maleki et al with predictable results because the known technique of having each array location coupled to a different detector as taught by Stabile et predictably results in an arrangement of the detectors suitable for signal detection.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 1-3 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8-22, and 26-28 of U.S. Patent No. 7,491,491 B2. Although not identical, the '491 claims describe the same limitations as the instant claims; namely, a sensor comprising an optical carrier (i.e., fiber), microspheres, immobilized oligonucleotides, and resonance shifts. For example, the limitations of instant claim 3 are met by claims 1-2 of the '491 patent. The additional limitations of the '491 claims are encompassed by the open claims language "comprising" found in the instant claims.

24. Claims 1-3, 6-9, 14-16, 19-22, and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-9 of copending Application No. 12/350,000 in view of Maleki et al (U.S. Patent Application Publication No. US 2002/0097401, filed 8 August 2001).

Both sets of claims are drawn to a system comprising a sensor comprising an optical carrier, a microsphere having a receptor, a light source, a detector and a means for determining the presences of an analyte substance (i.e., a processor). The additional limitations of the '000 claims are encompassed by the open claim language "comprising" found in the instant claims.

The '000 claims do not require the receptors to be oligonucleotides.

However, Maleki et al teach a sensor and system comprising an optical carrier in the form of an optical fiber (paragraph 0032). The sensor further comprises two or more optical cavities in the form of multiple WGM (i.e., whisper gallery mode) cavities that form a detector array (paragraph 0048). The optical cavities are optically coupled to the optical carrier because signals from the WGM are optically detected (Figure 3). The exterior surface of the WGM (i.e., optical) cavity is coated with a reactive surface in the form of a DNA molecule (i.e., an oligonucleotide; paragraph 0045). Because each WGM (i.e., optical) cavity is coated with a different reactive surface for a different analyte (i.e., a different DNA oligonucleotide for a different DNA analyte; paragraphs 0048 and 0045), each of the optical cavities has a surface having an oligonucleotide complementary to one of the at least two target substances. Application of light causes resonance within each of the optical cavities (paragraph 0006). The additional limitation

of claims 2-3, 6-9, 14-16, 19-22, are discussed above in Section 17. Maleki et al also teach the use of nucleic acids has the added advantage of allowing the sensor to have use with samples of a biological origin (paragraph 0041). Thus, Maleki et al teach the known technique of having a sensor having oligonucleotides thereon.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the '000 claims so that the receptors are oligonucleotides in accordance with the teachings of Maleki et al to arrive at the instantly claimed sensor and system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a sensor and system having the added advantage of allowing use of the sensor in biological assays as taught by Maleki et al (paragraph 0041). In addition, it would have been obvious to the ordinary artisan that the known technique of using oligonucleotides as receptors as taught by Maleki et al could have been applied to the system of the '000 claims with predictable results because the known technique of using oligonucleotides as receptors as taught by Maleki et al predictably results in receptors suitable for biological assays.

This is a provisional obviousness-type double patenting rejection.

25. Claims 1-2, 4-15, 17-27, 31, and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-9 of copending Application No. 12/350,000 in view of Boyd et al (U.S. Patent Application Publication No. US 2004/0023396 A1, filed 14 November 2002).

Both sets of claims are drawn to a system comprising a sensor comprising an optical carrier, a microsphere having a receptor, a light source, a detector and a means for determining the presences of an analyte substance (i.e., a processor). The additional limitations of the '000 claims are encompassed by the open claim language "comprising" found in the instant claims.

The '000 claims do not require the receptors to be oligonucleotides.

However, Boyd et al teach a sensor comprising optical carrier 14 and an optical cavity in the form of a resonator 20 (Figure 1A). The sensor has multiple resonators (i.e., optical cavities) on the carrier (i.e., waveguide; paragraph 0046). Each resonator surface has different oligonucleotide probes thereon (i.e., for different target nucleotide chain analytes; paragraphs 0030-0033). Light is applied to the carrier, and a shift (i.e., change) in resonance is detected (Abstract). Boyd et al also teach the additional limitation of claims 2, 4-15, 17-27, 31, and 33 as discussed above in Section 17. Boyd et al further teach oligonucleotides have the added advantage of allowing detection of biological pathogens (paragraph 0004). Thus, Boyd et al teach the known technique of having a sensor having oligonucleotides thereon.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the '000 claims so that the receptors are oligonucleotides in accordance with the teachings of Boyd et al to arrive at the instantly claimed sensor and system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a sensor and system having the added advantage

of allowing detection of biological pathogens as taught by Boyd et al (paragraph 0004). In addition, it would have been obvious to the ordinary artisan that the known technique of using oligonucleotides as receptors as taught by Boyd et al could have been applied to the system of the '000 claims with predictable results because the known technique of using oligonucleotides as receptors as taught by Boyd et al predictably results in receptors suitable for biological assays.

This is a provisional obviousness-type double patenting rejection.

Conclusion

26. No claim is allowed.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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